

## AMENDMENTS TO THE CLAIMS

1. (Previously presented) A system for the processing and separation of biological fluids into components, comprising a set of containers for receiving the biological fluid to be separated and the separated components, and optionally one or more additional containers for additive solutions, and a hollow centrifugal processing chamber rotatable about an axis of rotation and having an axial inlet/outlet for the biological fluid to be processed and for the processed components of the fluid, the processing chamber containing an axially movable member which defines a separation space of variable size for receiving biological fluid, the member being axially movable to intake a selected quantity of biological fluid to be processed into the separation space via said inlet and to express processed biological fluid components from the separation space via said outlet, and means for monitoring the position of the axially movable member to thereby control the amount of intaken biological fluid and the expression of separated components, the system further comprising a distribution valve arrangement for establishing selective communication between the processing chamber and selected containers or for placing the processing chamber and containers out of communication, the system comprising means for controlling operation of the system in two operational modes, a separation mode and a non-separation transfer mode, wherein:

- in the separation mode fluids can be intaken into the processing chamber while the chamber is rotating or stationary, fluid intaken into the chamber is centrifuged and separated into components, and the separated components expressed while the chamber is rotating or, optionally, for the last separated component, while the chamber is stationary; and

- in the transfer mode the processing chamber intakes fluid and expresses fluid with the chamber stationary, the valve actuation arrangement being actuatable to transfer amounts of fluid from one container to another via the processing chamber, by axially moving the member, without

centrifugation or separation of the fluid into components, and said means for monitoring the position of the axially movable member controls the amounts of non-separated fluids transferred.

2. (Previously presented) The system of claim 1, wherein the distribution valve arrangement comprises a set of rotational stopcock valves arranged in a manifold array, or a multiport rotational valve.

3. (Previously presented) The system of claim 1, wherein the distribution valve arrangement comprises a plurality of stopcock valves connected to tubing lines interconnecting the set of containers, the optional additional containers, the processing chamber and further stopcock valves, each stopcock valve comprising a rotatable stopcock valve member having a shaft associated with drive means, said shaft being rotatable to selectively connect or disconnect the stopcock valve's tubing lines.

4. (Previously presented) The system of claim 3, comprising means for allowing insertion of each stopcock valve only in a defined angular alignment of the rotatable stopcock valve member.

5. (Previously presented) The system of claim 1, wherein the distribution valve arrangement comprises a multiport valve comprising a central rotor rotatably mounted in an annular stator, the rotor having a central port connected to the processing chamber and leading to the rotor outer periphery, and the stator having a plurality of ports at selected angular locations each connected to a container and each leading into the inner periphery of the annular stator, the central port of the rotor being connectable to selected ports of the stator, or disconnected, by rotation of the rotor.

6. (Previously presented) The system of claim 1, wherein the movable member is a piston fluid-tightly movably mounted in a generally-cylindrical centrifugal processing chamber.

7. (Previously presented) The system of claim 6, further comprising optical means for monitoring the position of the piston, comprising an alignment of light emitting elements generally parallel to the piston axis, and an alignment of light receiving elements generally parallel to the piston axis, the receiving elements being arranged to receive light from the emitting elements transmitted through or past the piston or reflected by the piston, and to deliver a signal representative of the piston's position.

8. (Previously presented) The system of claim 7, wherein the receiving elements are arranged to deliver said signal to means for moving the piston and means for controlling the piston's position.

9. (Previously presented) The system of claim 1, comprising an optical sensor monitoring fluid in the tubing line connected to the axial inlet/outlet, for stopping the intake of biological fluid when the tubing line is empty during the intake mode and/or for providing a signal for switching the distribution valve arrangement in the extraction mode.

10. (Previously presented) The system of claim 1, wherein the axial inlet/outlet comprises a rotatable seal mountable in a stationary housing, said seal being operable for positive and negative pressure conditions in the rotatable chamber.

11. (Previously presented) The system of claim 1, wherein the processing chamber is mounted for rotation about its axis by means of bearings at opposite ends of the chamber, one end of the chamber being associated with means for rotating the chamber by contacting the chamber's bottom with a rotary disc without any support at the chamber periphery.

12. (Previously presented) The system of claim 1, wherein the means for controlling operation of the system in said two operational modes comprises a microprocessor based control system controlling an automated protocol.

13. (Previously presented) A method of processing and separating biological fluids in a system according to claim 1, the method comprising:

separating a biological fluid with the system operating in the separation mode, by intaking fluid into the processing chamber while the chamber is rotating or stationary, centrifuging fluid intaken into the chamber to separate the fluid into components, and expressing the separated components while the chamber is rotating or possibly, for the last component, while the chamber is stationary; and

transferring fluid between containers with the system operating in the transfer mode, by intaking fluid into the processing chamber with the chamber stationary, actuating the valve distribution arrangement to transfer an amount of fluid from one container to another via the processing chamber, by moving the member, without centrifugation or separation of the fluid into components, and monitoring the position of the movable member to control the amount of non-separated fluid transferred.

14. (Previously presented) The method of claim 13, wherein a component of the biological fluid is separated into a given container, the amount of said component separated into the given container being controlled by monitoring the position of said member, and an additive solution is transferred from an additional container to said given container via the processing chamber in said transfer mode, the amount of additive solution transferred being calculated as a function of the amount of said separated component in the given container.

15. (Previously presented) The method of claim 13, wherein a density gradient product and blood are introduced into the processing chamber, and a component of the biological fluid is separated into a given container and its collection is completed when the density gradient appears.

16. (Previously presented) The method of claim 13, wherein operation of the system in said two operational modes is controlled according to an automated protocol by a microprocessor based control system.

17. (Previously presented) A disposable set for collecting and separating selected quantities of biological fluids comprising the centrifugal processing chamber of a system according to claim 1, wherein the inlet/outlet of the centrifugal processing chamber is connected to a container of biological fluid, an additional container containing an additive solution, a plurality of containers for receiving the separated components of the biological fluid, interconnected by a distribution valve arrangement comprising a set of rotational stopcock valves arranged in a manifold array, or a multiport rotational valve.

18. (Currently amended) The disposable set of claim 17, wherein the distribution valve arrangement comprises a plurality of stopcock valves as defined in claim 3 connected to tubing lines interconnecting the set of containers, the optional additional containers, the processing chamber and further stopcock valves, each stopcock valve comprising a rotatable stopcock valve member having a shaft associated with drive means, said shaft being rotatable to selectively connect or disconnect the stopcock valve's tubing lines.

19. (Currently amended) The disposable set of claim 17, wherein the distribution valve arrangement comprises a multiport valve as defined in claim 3 comprising a central rotor rotatably mounted in an annular stator, the rotor having a central port connected to the processing chamber and leading to the rotor outer periphery, and the stator having a plurality of ports at selected angular locations each connected to a container and each leading into the inner periphery of the annular stator, the central port of the rotor being connectable to selected ports of the stator, or disconnected, by rotation of the rotor.

20. (Currently amended) ~~A method comprising use of the system~~ The method of claim ~~1~~ 13, for processing variable volumes of biological fluid from 10 ml up to the maximum volume of the separation chamber, and for adding an additive solution to the separated components.

21. (Currently amended) ~~The method according to~~ of claim ~~20~~ 13, for separation of stem cells from blood and mixing the separated stem cells with a preservative solution.

22. (Previously presented) The method according to claim 21, for separation of hematopoietic stem cells from umbilical cord blood, from an apheresis collection, or from a bone marrow aspirate.